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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,241	02/27/2004	Bent Formby		4809
7590	06/15/2005		EXAMINER	
Waikiwi Corporation 244 Oldwoods Road. Franklin Lakes, NJ 07417				JOHNSON, JERROLD D
		ART UNIT		PAPER NUMBER
		3728		

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/787,241	FORMBY, BENT	
	Examiner	Art Unit	
	Jerrold Johnson	3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 February 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-30 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>27 Feb. 2004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the limitations of claims 14 and 15 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 20 is objected to because of the following informalities: Claim 20 cannot depend from claim 1, but must instead depend from claim 19, as claim 20 recites "the container" which is a limitation set forth previously only in claim 19. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 10-17, 22-26, 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Liedtke US 5,686,112.

Liedtke discloses a disposable dispensing apparatus for storage and dispensing of a topically applied medicament comprising a blister pack having a plurality of wells, wherein the medicament is incorporated within a solution for topical administration and contains a biologically active substance. Leidtke further discloses indicia 4, which can be numeric or color.

It is noted that the specific contents of the indicia in the current claims do not confer patentable limitations on the claims, and fall under the category of printed matter in that no new and unobvious functional relationship exists between the printed matter and the substrate (the dispensing apparatus).

In the determination of whether the printed matter is functionally related to the container, reference is made to the following two Federal Circuit decisions: *In re Gulack*, 703 F.2d. 1381 [217 USPQ 401] (Fed. Cir. 1983), and *In re Ngai* 70 USPQ 2d 1862 (CA FC 2004).

Quoting Gulack, "The bare presence or absence of a specific functional relationship, without further analysis, is not dispositive of obviousness. Rather, the critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate." Id. at 1386.

The CAFC determined that in Gulack there was not merely a functional relationship between the printed matter and the substrate, but that the printed matter and the substrate were functionally interrelated, and that there was a new and unobvious functional relationship between the substrate (the container) and the instructions.

The CAFC stated within the *in re Ngai* decision "In Gulack, the printed matter would not achieve its educational purposes without the band, and the band without the printed matter would similarly be unable to produce the desired result." Id. at 1864.

In the present application, like Ngai, there is no new and unobvious functional relationship between the substrate (the dispensing apparatus) and the printed matter

(indicia). In Ngai, the court stated that "the printed matter in no way depends on the kit, and the kit does not depend on the printed matter." Similarly, in the present application, the dispensing apparatus is suitable to perform the function of a dispensing apparatus in the manner described in the specification irrespective of the indicia.

Accordingly, although an art rejection has been set forth in the rejection of the specific recitations or the indicia within the claims, it is understood that a teaching of *any* indicia would suffice to reject these limitations.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liedtke US 5,686,112 and Examiner Official Notice.

Liedtke discloses 28 day time period, but not 30 day.

30 day time periods for pharmaceuticals are as well known as 28 day time periods, and it is further known that many women are on a 30 day cycle.

Accordingly, it would have been obvious to have made the apparatus of Liedtke in a 30 day time period to accommodate the potential users of the medicament that are on a 30 day cycle.

Claims 7-9 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liedtke in view of Hughes US 6,139,873 and McDaniel US 2002/0120225.

Liedtke does not disclose sequential colors being used in the solution.

Hughes discloses adding colors to hormonal treatments for color coding purposes and also discloses topical ointments in col. 14, lines 34-63. Hughes does not disclose sequential colors.

McDaniel discloses in Fig. 9 and page 6 the use of sequential colors within a multi step process for identification purposes.

It would have been obvious to modify the apparatus of Liedtke with the teachings of Hughes and McDaniel so as to provide a multi-day drug blister pack where the user can easily visually identify the correct daily dose via visual identification through the identification of a color within a color sequence.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liedtke in view of Schaefer DE 198 31 263 A1 (US 6,630,149 is the corresponding US Patent and serves as the English language translation).

Liedtke does not disclose non-aqueous solution medicaments.

Schaefer discloses the combination of aqueous solution medicaments and non-aqueous solution medicaments.

It would have been obvious to have packaged both aqueous solution medicaments and non-aqueous solution medicaments in a single blister pack, as taught

by Schaefer, so as to minimize the packaging required, and to minimize the potential that the different medicaments would be separated.

Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leidtke in view of Haber US 5,405,011 and Hermelin et al US 6,375,956.

Leidtke does not show rolled configurations or a container for the blister pack.

Haber discloses a rolled configuration in Fig. 2,

Hermelin discloses a container in Fig. 3. Multi-compartment containers for blister packs are well known.

It would have been obvious to provide the blister pack of Leidtke in a rolled configuration so as to fit into special cylindrical dispensers as taught by Haber. It also would have been obvious to provide the blister pack of Leidtke in a container, as taught by Hermelin so as to protect the blister pack during transport.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerrold Johnson whose telephone number is 571-272-7141. The examiner can normally be reached on 9:30 to 6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 571-272-4562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JDJ



Mickey Yu
Supervisory Patent Examiner
Group 3700